

*ISPE Boston Area Chapter Presents:*  
**AUTOMATION:**  
**At the Crossroads with IT Interfaces**

**Thursday, May 16, 2013**

5:30 pm to 8:30 pm

*Genzyme Center*

500 Kendall Street, Cambridge, MA 02142

**PROGRAM SUMMARY:**

Should process control automation be interfaced with IT infrastructure? To answer that question, perhaps we can learn from the sage advice of Yogi Berra, who famously once said, "When you come to a fork in the road...take it." When we consider where process control automation is headed and the demands of new paradigms like knowledge management and Stage 3-Continued Process

Verification, such interfaces are quickly becoming a necessity rather than an option. Attendees will learn about the changing role of the automation engineer, as well as some of the drivers and issues.

**PRESENTATION ONE:**

**Process Data Management and the Changing Role of the Automation Engineer**

As the need for business and process data grows, companies are commissioning more specialized computerized systems, sometimes with a great deal of overlap leading to redundant data being stored in multiple systems. ANSI/ISA95 (Enterprise-Control System Integration) addresses this problem by setting standards for communications within the enterprise layers of manufacturing and operations. The role of the automation engineer is being transformed into that of a business analyst in order to streamline processes such as materials management, computerized maintenance, and procurement. Service Oriented Architecture, Web Services, and OPC communications will be discussed. Systems to be explored include DCS, MES, EDMS, EQMS, CMMS, and Plant Historians.

**SPEAKER ONE:**

**Jordan Croteau** is an Automation Engineer in Biogen Idec Cambridge Manufacturing Engineering. Jordan has served as technical lead for numerous projects on process automation and control and IT systems, with a process data management focus. Before Biogen Idec, Jordan spent three years working for automation integrators and process skid manufacturers. Jordan earned a Bachelor of Science in Chemical Engineering from Worcester Polytechnic Institute, and is a member of the International Society of Automation (ISA) and an Information member of the ISA95, ISA18, and ISA100 committees.

**PRESENTATION TWO:**

**Implementing an Equipment Monitoring System with an Operations Information Infrastructure**

This presentation describes the installation of an automated Equipment Monitoring System providing "review by exception" electronic reports with automated routing and e-signature approvals to replace an existing manual paper-based GMP record for logging equipment temperature readings, and related process data and information.

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**PRESENTATION TWO Continued:**

The execution of this project required the implementation of a site-wide Operations Information Infrastructure which will also be discussed as the basis on which future “electronic initiative” application projects will be integrated.

**SPEAKER TWO:**

**Kenneth S. Kovacs** is the QA Business Systems Manager at Fujirebio Diagnostics, Inc. in Malvern, PA and a Certified Management Consultant (CMC). He has in-depth knowledge in Life Sciences Industry operations, manufacturing, and technology transfer through 35 years of experience working with companies including Johnson & Johnson, TAVA Technologies, and Rockwell Automation.

Ken is an active member of ISPE and GAMP America’s MES SIG. He is an original member of the ISA-95 committee that developed the “Enterprise-Control System Integration” international standard, a past Director of ISA’s Food and Pharmaceutical Industries Division, and a co-author of both the textbook “Automation and Validation of Information in Pharmaceutical Processing” and the GAMP® Good Practice Guide: Manufacturing Execution Systems Control and Compliance”. Ken has a Bachelor of Engineering degree from Villanova University and an MBA from Xavier University.

**SPEAKER THREE:**

**Glenn Restivo** is the Director of Business Development Life Sciences, Chemicals, Food and Nutrition for M+W Automation. His role is to develop and promote automation and manufacturing IT solutions for pilot and commercial manufacturing addressing industry, business and regulatory challenges. He focuses his efforts on meeting the customer’s time to market, minimizing project risk, optimizing solutions and using state of the art technology that supports project lifecycle and asset management.

He received a bachelor’s degree in chemical engineering from Stevens Institute of Technology in Hoboken, New Jersey. In addition, he actively participates with the International Society for Pharmaceutical Engineers (ISPE), MIT’s Center for Biomedical Innovation (CBI), Rutgers Engineering Research Center (ERC), Next Generation Pharma Workshops and has articles on PAT/QbD and RFID published in key industry trade magazines.

**MEETING MANAGER:**

**Robert J. Wherry, Principal Consultant, Strategic Compliance Services, PAREXEL International**



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**PROGRAM SCHEDULE:**

5:30 – 6:30 PM Registration & Networking Reception

6:30 – 8:30 PM Welcome & Program



**REGISTRATION FEES:**

**Registration by 05/09/2013**

**After 05/09/2013**

<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Non-members **	\$95	\$115
<input type="checkbox"/> Students	FREE	FREE

\*\* Attendees may only attend one program as a non-member.

**REGISTRATION IS NOW OPEN ONLINE!**

Don't waste time filling in the form! Register online at [www.ISPEBoston.org/Events](http://www.ISPEBoston.org/Events).

Pay by credit card OR check.

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Do you wish to opt out of being listed on the attendee roster:

Company: \_\_\_\_\_ Member #: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_ Email: \_\_\_\_\_

**PAY BY CREDIT CARD:**  Visa  MasterCard  American Express

Card #: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Cardholder Name (as it appears on card): \_\_\_\_\_

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Payment may be mailed to: ISPE, Boston Area Chapter, 411 Waverley Oaks Road, Suite 331B, Waltham, MA 02452

Telephone: 781-647-ISPE (4773) ☒ Fax: 781-647-7222 ☒ Email: [office@ispeboston.org](mailto:office@ispeboston.org)

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER May 9th ARE SUBJECT TO BILLING\*\***

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**DIRECTIONS AND PARKING:**

**From the Expressway North/South**

Take the exit for Storrow Drive  
Follow Storrow Drive to the Kendall Square/Government Center exit  
Follow the signs for Kendall Square  
Cross the Longfellow Bridge and into Cambridge  
After crossing the river, take a right at the first set of lights onto Third Street  
Turn right onto Kendall Street  
The parking garage is on your right

**From the Massachusetts Turnpike (I-90 Eastbound)**

Take the Mass Turnpike East  
Take Exit 18 (Allston/Cambridge)  
Follow signs toward Cambridge/Somerville  
The Doubletree Guest Suites Hotel will be on your right  
At the traffic light take a right onto Storrow Drive  
Do not cross the river  
Take the Kendall Square/Government Center exit off Storrow Drive  
Follow the signs for Kendall Square, bearing left around the rotary and across the Longfellow Bridge into Cambridge  
After crossing the river, take a right at the first set of lights onto Third Street  
Turn right onto Kendall Street  
The parking garage is on your right

**From the "T"**

Take the Red Line to the Kendall Square stop  
When you exit the station, you will be on Main Street  
Walk East - towards Boston - and you will see a traffic light at the corner of Broadway and Third Street  
Cross at the intersection and walk down Third Street  
Take your first right onto Kendall Street  
Genzyme Center is the first building on the left

